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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,677	03/19/2007	Allen Rosenspire	66174-0006	4698

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EXAMINER	
FERNANDEZ, SUSAN EMILY	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
10/07/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/585,677	ROSENSPIRE ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-11 and 13-44* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-11 and 13-44* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2011, has been entered.

Claim 44 is new. Claims 1-11 and 13-44 are pending and examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 13, 14, 16-18, 20, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kindzelskii et al. (Biochimica et Biophysica Acta. 2000. 1495: 90-111) in light of the Journal of Cell Science (2001. 114: 1515-1520).

Kindzelskii et al. discloses that "...external pulsed DC electric fields phase-matched to endogenous cellular oscillations lead to enhanced metabolic oscillations or metabolic resonance and cell extension" (page 91, first column, last paragraph). Furthermore, "metabolic resonance is accompanied by exaggerated cell extension" (page 97, first column, last paragraph). Kindzelskii et al. found that "phase-matched electric fields induce metabolic resonance in cells and greatly

exaggerate cell extension or shape change" (page 99, first paragraph). As the electric fields are phase matched to the endogenous cellular oscillations, the electric field has a frequency within 10% of the frequency of the internal NAD(P)H oscillation frequency within the cells, thus meeting limitations in instant claim 11.

It is noted that electric fields applied at NAD(P)H autofluorescence troughs trigger metabolic resonance and enhance spreading, whereas electric fields applied at NAD(P)H autofluorescence crests disrupt oscillations and the spreading of nascent pseudopods (page 103, first paragraph). Metabolic resonance is exhibited by NAD(P)H autofluorescence oscillations that grow in amplitude (page 94, last paragraph and Figure 10 on page 101, where magnetic resonance is triggered for electric fields of 2×10^{3} V/m to 1×10^{-4} V/m which meets the requirements of instant claim 13 and the electric field intensity limitation of instant claim 44). See also Figure 4, which indicates that "When an electric field (arrows) is applied at NAD(P)H autofluorescence troughs, the metabolic oscillations increase in amplitude, illustrating metabolic resonance, in the absence and presence of FMLP (e, f)." Note further that Kindzelskii teaches that the pulsed DC electric field has a pulse of 20 milliseconds (page 94, last paragraph and the legend of Figure 10), thus meeting the pulse length limitation of instant claim 44.

The electric fields can also be applied at the NAD(P)H autofluorescence crests (page 103, first column). It can be seen from Figure 13 that the spreading neutrophils become spherical after exposure to such an electric field (see (C) and (D)). Therefore, there is also a change in neutrophil shape to a spherical morphology, as required by the instant claims. Further still, the electric field is applied at other than the minima of the NAD(P)H oscillation frequency and at the oscillation crests, thus meeting the requirements of instant claims 14, 17, and 18.

It is also noted that the Kindzelskii study is performed on neutrophils isolated from the peripheral blood of normal healthy adults (page 91, second column, first full paragraph). Furthermore, the pulsed DC field is applied on migrating cells (page 94, second column, last paragraph). As pointed out in the Journal of Cell Science, cells assuming polarized morphology are migratory (page 1516, second column, second full paragraph). Therefore, the application of electric fields of the Kindzelskii study is performed on polarized cells.

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenpire et al. (Biophysical Journal. 2000. 79(6): 3001-3008) in view of Kindzelskii et al. (Biochimica et Biophysica Acta. 2000. 1495: 90-111).

Rosenpire et al. discloses monitoring NAD(P)H autofluorescence in spherical and polarized neutrophils (page 3001, second to last paragraph and Figure 1), where the neutrophils are purified from the blood of healthy individuals (page 3001, second column, second paragraph). The reactive oxygen metabolite (ROM) production, an important neutrophil effector function, is controlled by NAD(P)H metabolic oscillation (page 3001, first column). Electric fields of square-wave voltage forms were applied, as well as electric fields of sinusoidal voltage forms (page 3001, last paragraph). Figure 6 shows the effects of electric fields generated by a series of three properly phase- and frequency-matched sinusoidal voltage forms which have sequentially established resonance with NAD(P)H oscillations in an adherent neutrophil (page 3005, first full paragraph). Clearly, the electric field has a frequency within about 10% of the frequency of internal NAD(P)H oscillations with the cell, and is applied for a time period equal to three periods of NAD(P)H oscillation, thus meeting limitations in instant claims 2, 4, 5, 11. The adherent neutrophils are polarized cells (page 3003, first paragraph). It is pointed out in Figure 6 that "initial application of the AC voltage was begun at a NAD(P)H minimum" and that the "AC electric fields resonate with naturally occurring NAD(P)H oscillations in human neutrophils." From Figure 6, it is clear that the amplitudes of NAD(P)H oscillations increase when the electric field in sinusoidal AC voltage form is applied. Electric field strengths applied include 9.0×10^{-2}, 4.5×10^{-1}, and 2.3 V/m (Figure 6), thus meeting limitations in instant claims 3 and 13.

Rosenpire et al. does not expressly disclose that the shape of the converted polarized eukaryotic cells is converted to a spherical morphology.

Kindzelskii et al. discloses that "...external pulsed DC electric fields phase-matched to endogenous cellular oscillations lead to enhanced metabolic oscillations or metabolic resonance and cell extension" (page 91, first column, last paragraph). Furthermore, "metabolic resonance is accompanied by exaggerated cell extension" (page 97, first column, last paragraph). Kindzelskii et al. found that "phase-matched electric fields induce metabolic resonance in cells and greatly exaggerate cell extension or shape change" (page 99, first paragraph). It is noted that electric fields applied at NAD(P)H autofluorescence troughs trigger metabolic resonance and enhance spreading, whereas electric fields applied at NAD(P)H autofluorescence crests disrupt oscillations and the spreading of nascent pseudopods (page 103, first paragraph). Metabolic resonance is exhibited by NAD(P)H autofluorescence oscillations that grow in amplitude (page 94, last paragraph and Figure 10, where magnetic resonance is triggered for electric fields of 2 $x10^{3}$ V/m to 1 x 10^{-4} V/m). The electric fields can also be applied at the NAD(P)H autofluorescence crests (page 103, first column). It can be seen from Figure 13 that the spreading neutrophils become spherical after exposure to such an electric field (see (C) and (D)). Therefore, there is also a change in neutrophil shape to a spherical morphology. Further still, the electric field is applied at other than the minima of the NAD(P)H oscillation frequency and at the oscillation crests, thus meeting the requirements of instant claims 14, 17, and 18. Kindzelskii et al. indicates that "...by manipulating the phase differences between the applied electric field and a cell's endogenous metabolic oscillations, one can affect the production of oxidants in parallel with cytoskeletal assembly and NAD(P)H amplitudes" (page 104, first column, first paragraph).

It would have been obvious that the electric fields of sinusoidal voltage forms applied to the polarized (adherent) cells as taught in Rosenpire et al. would have resulted in a change in cell shape to a spherical morphology. A change in cell shape to a spherical morphology would have occurred since in Figure 6 of Rosenpire et al., it is clear that the amplitudes of NAD(P)H oscillations increase when the electric field in sinusoidal AC voltage form is applied. As pointed out in Kindzelskii et al., metabolic resonance is exhibited by NAD(P)H autofluorescence osciallations that grow in amplitude, and a showing of metabolic resonance is accompanied by exaggerated cell extension, and hence a change in cell shape to a spherical morphology. Therefore, instant claims 1-5 and 7-9 are rendered obvious.

A holding of obviousness is clearly required.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenpire and Kindzelskii as applied to claims 1-5 and 7-9 above, and further in view of Gordon (US 4,758,429).

As discussed above, Rosenpire and Kindzelskii render claims 1-5 and 7-9 obvious. However, the references differ from the claimed invention in that they do not teach that the electric field is applied by means of magnetic induction. However, electromagnetic field is a known means for applying an electric field to cells. See Gordon, claim 1. The application of an electromagnetic field entails application of an electric field by means of magnetic induction. It would have been obvious to the person of ordinary skill in the art to have used an electromagnetic field since the electromagnetic field provides an electric field as required by Rosenpire et al. Thus, claim 6 is rendered obvious.

Claims 10, 11, 13-20, 38-41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kindzelskii in view of Gordon, and in light of the Journal of Cell Science.

As discussed above, Kindzelskii in light of the Journal of Cell Science anticipates instant claims 10, 11, 13, 14, 16-18, 20, and 44. However, Kindzelskii differs from the claimed invention in that it does not teach that the electric field is applied by means of magnetic induction. However, electromagnetic field is a known means for applying an electric field to cells. See Gordon, claim 1. The application of an electromagnetic field entails application of an electric field by means of magnetic induction. It would have been obvious to the person of ordinary skill in the art to have used an electromagnetic field since the electromagnetic field provides an electric field as required by Kindzelskii. Thus, instant claims 15 and 19 are rendered obvious. Furthermore, it would have been a matter of routine experimentation to have varied that pulse trains of the magnetic induction. Thus, instant claims 38-41 are rendered obvious.

A holding of obviousness is required.

Claims 21, 22, 24-26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 4,758,429).

Gordon discloses a process for the treatment of arthritis (an inflammatory, pathological condition in mammals) wherein a relatively low frequency alternating, oscillating and/or pulsed electromagnetic field is provided to the joint space (claim 1). The application of an electromagnetic field entails application of an electric field by means of magnetic induction.

Gordon does not expressly disclose that the electric field applied to the tissue is at least 10^{-2} V/m or at least 10^{-5} V/m. However, the selection of a suitable field strength would have been a matter of routine experimentation on the part of the skilled artisan.

A holding of obviousness is clearly required.

Claims 21-37, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Litovitz (US 5,968,527).

As discussed above, Gordon renders claims 21, 22, 24-26, and 31 obvious. However, it does not expressly disclose that a coil applicator is used, or that the magnetic induction comprises a time-varying magnetic field in square wave and sawtooth wave forms.

Litovitz discloses using time-varying fields, such as electric and magnetic fields, on organs (column 7, lines 54-60). The periodic signals emitted may be triangular waves, square waves, and pulse trains (column 15, lines 6-9). Moreover, a coil applicator may be used (column 14, lines 31-38).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used time-varying fields with square and sawtooth wave forms (for the magnetic field) and to have used a coil applicatior when practicing the Gordon invention. One of ordinary skill in the art would have been motivated to do this since there would have been a reasonable expectation of success of changing these features of the Gordon invention to still obtain an effect on tissue. These features still would have been suitable for obtaining an electromagnetic field as required by the Gordon invention. Thus, claims 23, 27-30, and 32-37 are rendered obvious. Furthermore, in the practice of the Gordon invention, polarized eukaryotic

cells would have been amongst the joint cells. It would have been obvious to have varied pulse trains through routine experimentation. Thus, claims 42 and 43 are rendered obvious.

A holding of obviousness is clearly required.

Claims 25-27 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trock (Journal of Rheumatology. 1994. 21: 1903-1991).

Trock discloses the treatment of osteoarthritis, a known inflammatory disease and also a known pathological condition, by the application of pulsed electromagnetic field on the cells of the affected tissue of human patients (abstract and first column of page 1904). Since the inflammatory disease is treated by the pulsed electromagnetic field, the inflammatory condition is mitigated in the human patients. Given that the application of an electromagnetic field entails application of an electric field by means of magnetic induction and that a DC electric current is used, Trock teaches the application of a pulsed electric field to a tissue comprising an inflammatory condition of a human patient wherein the electric field is applied by means of magnetic induction. Furthermore, the device for creating and applying the pulsed electromagnetic field comprises a coil (page 1904, first column, third and fourth paragraphs), thus meeting the limitation of instant claim 27.

Trock differs from the claimed invention in that it does not expressly disclose that the electric field applied to the tissue is at least 10^{-2} V/m or at least 10^{-5} V/m. However, the selection of a suitable field strength would have been a matter of routine experimentation on the part of the skilled artisan.

A holding of obviousness is clearly required.

Claims 21-37, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trock as applied to claims 25-27 and 31 above, and further in view of Polk (Chapter 91 in The Biomedical Handbook: Second Edition. Ed. Joseph D. Bronzino Boca Raton: CRC Press LLC, 2000.) and Litovitz.

As discussed above, Trock renders instant claims 25-27 and 31 obvious. However, Trock does not expressly disclose that the electric field is of sinusoidal frequency or that the magnetic induction comprises a time-varying magnetic field.

Polk provides a review of the therapeutic applications of pulsed and sinusoidal electric and magnetic fields. Polk indicates that extremely weak sinusoidal electric fields can have a profound effect on cells in vitro and can affect bone and cartilage development (Section 91.3). Moreover, Polk indicates that studies have been performed on the use of time-varying magnetic fields for the treatment of arthritis (first paragraph on second page of Chapter 91).

Litovitz discloses using time-varying fields, such as electric and magnetic fields, on organs (column 7, lines 54-60). The periodic signals emitted may be triangular waves, square waves, and pulse trains (column 15, lines 6-9). Moreover, a coil applicator may be used (column 14, lines 31-38).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used an electric field of sinusoidal frequency when practicing treating osteoarthritis with an electromagnetic field. One of ordinary skill in the art would have been motivated to do this since such electric fields were known to have an effect on cells in vitro and can affect bone and cartilage development. Furthermore, it would have been obvious to have

used time-varying magnetic fields with square and sawtooth wave forms when treating osteoarthritis with an electromagnetic field. One of ordinary skill in the art would have been motivated to do this because time-varying magnetic fields were of interest in the prior art for the treatment of arthritis. Thus, instant claims 21-24 and 28-30 and 32-37 are rendered obvious. Furthermore, in the practice of the invention rendered obvious by Trock, Polk, and Litovitz, polarized eukaryotic cells would have inherently been amongst the cells of the tissue being treated. It also would have been obvious to have varied pulse trains through routine experimentation. Thus, claims 42 and 43 are rendered obvious.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed February 17, 2011, have been fully considered but they are not persuasive. The applicant asserts that Kindzelskii does not appear to teach the claimed methods of effecting the conversion of the shape of polarized eukaryotic cells to spherical morphology by implementing and following each and every step and limitation of the methods as claimed. However, the rejection above outlines specifically each limitation of the instant claims which are taught by Kindzelskii. The applicant has not specified which specific limitations are not taught by Kindzelskii. Therefore, the rejection under 35 U.S.C. 102(b) over Kindzelskii is maintained for the reasons of record.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where

there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Applicant asserts the office action had not set out where the art indicates why the combination of the selected statements is desirable. However, with respect to the combination of Rosenpire with Kindzelskii, it is respectfully noted that Kindzelskii was combined to demonstrate the expected effect on the shape of the Rosenpire cells, as Kindzelskii teaches the relationship between NAD(P)H oscillation amplitude and cell shape. With respect to the purported desire to control ROM production so as to cease ROM production, it is noted that the argument in the prior office action regarding ROM production was with respect to rendering obvious claims 14, 17, and 18 over Rosenpire as a primary referency. However, in the instant office action, Rosenpire is no longer combined with other references to render obvious claims 14, 17, and 18.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, the 35 U.S.C. 103(a) rejections over Rosenpire, Kindzelskii, and Gordon are indeed proper.

In response to applicant's argument that Gordon is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Gordon is indeed in the field of the applicant's endeavor, with respect to claims 21-37, 42, and 44, since Gordon pertains to the application of an electric field to tissue comprising an inflammatory condition or pathological condition in a mammal. Though the application of electric field as taught in Gordon further comprises the use of particles, the instant claims do not prohibit the use of such particles or the presence of mediators for effecting the therapeutic effect of the electric field on the tissue cells. Claims 21-37, 42, and 44 broadly speak of the application of electric field to the cells being treated and therefore can encompass further steps and elements. Therefore, the rejections over Gordon must be maintained. Nevertheless, Trock has been provided as art to render obvious claims 21-37, 42, and 44.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1653

Susan E Fernandez
Examiner
Art Unit 1651

sef